Compliance Assistance Tool for Clean Air Act Regulations: Subpart GGG of40 CFR NESHAPS for Source Category Pharmaceutical Production

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Office of Enforcement and Compliance Assurance
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Compliance Assessment and Media Programs Division
Air, Hazardous Waste and Toxics Branch

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LIST OF ACRONYMS

ACT	Alternative Control Techniques Information Document (EPA, 1994)
APCD	Air Pollution Control Device
ASTM	American Society for Testing and Materials
BOD	Biological Oxygen Demand
BP	Boiling Point
CAA	Clean Air Act
CAS Number	Chemical Abstracts Service Number
CEF	Control Equipment Failures
CEMS	Continuous Emissions Monitoring System
CFR	Code of Federal Regulations
CH_4	Methane
CMS	Continuous Monitoring System
CO_2	Carbon Dioxide
CTG	Control Technology Guidelines (EPA, 1978)
CVS	Closed Vent System
CWA	Clean Water Act
DE	Design Evaluation
DOT	Department of Transportation
EC	Air Emissions Control
ED	Estimated Dose
EE	Emissions Estimation
EPC	Emission Potential Concentrations
EPA	U.S. Environmental Protection Agency
F_{bio}	Degradation Factor for biological treatment
Fm	Fraction measured
FDA	Food and Drug Administration
FID	Flame Ionization Detector
FR	Flowrate
gal	Gallon
GC	Gas Chromatography
GGG	subpart GGG to part 63 - NESHAP
H_2O	Water
HAPs	Hazardous Air Pollutants
HCl	Hydrogen Chloride
HDPE	High Density Polyethylene
HON	Hazardous Organic - NESHAP
IDS	Individual Drain System
I&M	Inspection and Maintenance
IWP	Improper Work Practices
Kb	Subpart of NSPS- requirements for storage tanks w/floating roofs
kg	Kilogram

lb	Pound
LDAR	Leak Detection and Repair
M^3	Cubic Meter
M21	Method 21
MACT	Maximum Achievable Control Technology
MDL	Method Detection Limit
MED	Median Effective Dose
MiBK	Methyl isobutyl Ketone
mmHg	millimeters Mercury
MW	megawatts
NAICS	North American Industrial Classification System
NESHAP	National Emission Standard for Hazardous Air Pollutants
NOC	Notification of Compliance
NOCSR	Notification of Compliance Status Report
NPDES	National Pollutant Discharge Elimination System
NSPS	New Source Performance Standards
O_2	Oxygen
O/O	Owner or Operator
P2	Pollution Prevention
Pa	Pascal
PEG	Polyethylene Glycol
PhRMA	Pharmaceutical Research and Manufacturers of America
PL	Production Levels
PMPU	Pharmaceutical Manufacturing Process Unit
POD	Point of Determination
ppm	Parts per million
ppmv	Parts per million volume
ppmw	Parts per million weight
PRV	Pressure Release Valve
PSHAP	Partially Soluble Hazardous Air Pollutants
psi	Pound per Square Inch
PT	Performance Testing
QA/QC	Quality Assistance/Quality Control
RCRA	Resource Conservation and Recovery Act
RE	Removal Efficiences
scfm	standard cubic feet per minute
SHAP	Soluble Hazardous Air Pollutants
SIC code	Standard Industrial Classification
SSM	Startup, Shutdown, or Malfunction
TOC	Total Organic Compounds
tpy	Tons per year
TSS	Total Suspended Solids
TTN	Technology Transfer Network (http://www.epa.gov/ttn/)
VHAP	Volatile Hazardous Air Pollutants
VOC	Volatile Organic Compounds

VP	Vapor Pressure
VS	Vapor Suppression
WMU	Waste Management Unit
WW	Waste Water
WWT	Wastewater Treatment

Chapter 2
Overview of the Regulations

2.1 Purpose of the Rule

The purpose of this EPA rule, proposed on April 2, 1997, promulgated on September 21, 1998 and amended on August 29, 2000 is to reduce air emissions of hazardous air pollutants (HAP) from both existing and new facilities that manufacture pharmaceutical products. EPA estimates that implementation of the rule will reduce HAP emissions from existing sources by approximately 24,000 tons per year. In addition, the controls put in place to comply with these MACT standards also will reduce volatile organic compounds (VOC) emissions. This will be accomplished primarily by limiting emissions from storage tanks, process vents, wastewater systems, and equipment leaks. This rule will lead to increased protection of the public by reducing emissions of chemicals that are harmful to human health and the environment.

Chapter 2 at a Glance

2.2 Statutory Background

This new regulation, subpart GGG to Part 63, is based on Congressional direction provided in section 112 of the Clean Air Act, which was amended in 1990. Section 112(b) contains a list of HAP to be regulated. The statutory list contains 188 substances and categories of substances designated as "hazardous air pollutants" that must be regulated. The list includes methylene chloride, methanol, toluene, and hydrogen chloride, four commonly-used chemicals in the pharmaceutical manufacturing industry.

The EPA used the set of 188 HAP, as directed under 112(c), to develop a list of source categories for which emission standards would be set. This list, published on July 16, 1992, included the pharmaceutical manufacturing industry. Therefore, EPA developed this National Emission Standard for Hazardous Air Pollutants (NESHAP) specifically for the pharmaceutical manufacturing industry.

Section 112(d) directs EPA to promulgate emissions standards that reflect use of the "maximum achievable control technology" (MACT). EPA must take into account "the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements....," when setting the standards. The statute directs EPA to develop standards for existing sources and for new sources. New source standards cannot be "less stringent than the emission control that is achieved in practice by the best controlled

similar source." The standard for existing sources should be no less stringent than the average emission control achieved by the best performing 12 percent of the existing sources. Therefore, the final rule specifies different standards for new and existing sources in some, but not all, cases.

NOTE: Whenever the terms "existing sources" or "new sources" are used in this document, this most often means "processes subject to existing source MACT" or "processes subject to new source MACT."

The pharmaceutical NESHAP rule is progressive in that it offers a pollution prevention standard for pharmaceutical manufacturers as an alternative to using add-on controls to limit emissions. Under the pollution prevention option, owners and operators can opt to reduce the overall consumption of HAPs in their processes. This option is available only for existing sources and does not apply to HAPs that are generated in the manufacturing process. The pollution prevention standard requires that owners reduce the production-indexed consumption of HAPs by 75%, using a baseline consumption factor calculated from data no earlier than 1987. The production-indexed consumption factor is expressed as kg HAP consumed/ kg product produced. A second pollution prevention alternative allows the owner or operator to reduce the production-indexed consumption factor by 50% AND use other add-on controls to achieve an overall 75% reduction. The pollution prevention option will be described in detail in a later chapter.

Sections of the Pharmaceutical MACT

63.1250 - Applicability - Defines affected sources that are subject to the rules and sources that are exempt and sets compliance deadlines.
63.1251 - Definitions - Provides definitions to terms as they are used in subpart GGG**.**
63.1252 - Standards: General - Specifies controls for closed vent systems, heat exchange systems, certain liquid streams, and certain halogenated vent streams controlled by combustion devices. Also presents pollution prevention as an alternative to achieving end-of-pipe reductions.
63.1253 - Standards: Storage Tanks - Specifies standards for storage tanks.
63.1254 - Standards: Process Vents - Specifies standards for process vents.
63.1255 - Standards: Equipment Leaks - Specifies work practices for pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, control devices, and closed-vent systems that are in HAP service (in contact with HAPs at a concentration $5% total HAP by weight) for at least 300 hours per year.
63.1256 - Wastewater Provisions - Specifies standards for wastewater tanks, surface impoundments, containers, individual drain systems, oil-water separators, treatment processes, and control devices. Provides control options for wastewater.
63.1257 - Test Methods and Compliance Procedures - Contains instructions for testing emissions from sources, and provides specific procedures for demonstrating initial compliance with standards for storage tanks, process vents, and wastewater.
63.1258 - Monitoring Requirements - Contains provisions for monitoring specified parameters to determine continued compliance. Discusses what constitutes violation of operating parameters and emission limits.
63.1259 - Recordkeeping - Provides instructions for keeping records of applicability determinations; startup, shutdown, and malfunction plans; operating parameters data, including emissions averaging data; applications for approval of construction or reconstruction; and leak detection and repair programs.
63.1260 - Reporting - Gives instructions on submittal of initial notification, applications for approval of construction or reconstruction, notification of continuous monitoring system (CMS) performance evaluation, Precompliance and Notification of Compliance Status reports, Periodic reports, notification of process changes, reports on startup, shutdown, and malfunction, leak detection and repair reports, emissions averaging calculations, and performance tests.
63.1261 - Delegation of Authority - Specifies which authorities cannot be delegated to States.

NOTE: The HAPs regulated in this rule also are subject to regulation under EPA's water program. New effluent guidelines and pretreatment standards for the pharmaceutical industry also were published on September 21, 1998. See these new regulations for further information (40 CFR Part 439).

2.3 Major Components of the Rule

The MACT regulations for the pharmaceutical industry contain eleven major sections. In addition to these standards, portions of Subpart A of Part 63 - National Emission Standards for Hazardous Air Pollutants for Source Categories- apply to the pharmaceutical manufacturing industry. The applicable Subpart A provisions are listed in Table 1 to Subpart GGG in the rule.

The complete text of the rule, including appended Tables, is available via Internet from:

http://www.epa.gov/fedrgstr/EPA-AIR/1998/September/Day-21/a23168a.htm

and

http://www.epa.gov/fedrgstr/EPA-AIR/2000/August/Day-29/a21195.htm

and

http://www.epa.gov/fedrgstr/EPA-AIR/2001/August/Day-02/a18879.htm

All three documents together comprise the complete text. Alternatively, an updated version of the Code of Federal Regulations is maintained through the Government Printing Office's website:

http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr63b_00.html

A summary of Table 1 is provided below. Refer to the full text of Table 1 in the regulations for more details.

Subpart A Provisions	Relevance to GGG
63.1 - Applicability	Confirms the general applicability of Part 63, but notes that where there are overlaps, subpart GGG takes precedence. Subpart GGG clarifies compliance dates specific to pharmaceutical operations. Confirms that, as a "major affected source," pharmaceutical manufacturing operations are subject to Title V permit requirements.
63.2 - Definitions	All definitions apply; additional ones are provided in Subpart GGG. Where there are overlaps, Subpart GGG takes precedence.
63.3 - Units and Abbreviations	All units and abbreviations apply; additional ones are provided in Subpart GGG.
63.4 - Prohibited Activities	All restrictions listed also apply to pharmaceutical manufacturing industry.

Subpart A Provisions	Relevance to GGG
63.5 - Construction and Reconstruction	Applies to pharmaceutical manufacturing operations. The terms "source" and "stationary source" are replaced with "affected source."
63.6 - Compliance with Standards and Maintenance Requirements	Most applies to pharmaceutical manufacturing operations; Subpart GGG specifies compliance dates for new and existing sources. Opacity and visible emission standards are not applicable. Subpart GGG provides instructions for compliance extensions.
63.7 - Performance Testing Requirements	Applies to pharmaceutical manufacturing operations. Subpart GGG specifies required testing and compliance procedures, as well as test methods specific to the industry. Substitute 150 days instead of 180 days in § 63.7(a)(2). A test plan must be submitted with the notification of performance test.
63.8 - Monitoring Requirements	Generally, monitoring requirements apply to pharmaceutical manufacturing operations; specific CMS requirements are provided in Subpart GGG, however. Provisions relating to continuous opacity monitoring systems (COMS) do not apply. References to calibration procedures are in §63.1258.
63.9 - Notification Requirements	General notifications requirements apply to pharmaceutical manufacturing operations. Notification of performance test 60 days before planned test date is applicable. Requirements relating to CMS and opacity or visible emissions standards are not applicable. Initial notification and performance evaluation requirements apply.
63.10 - Recordkeeping Requirements	General recordkeeping requirements apply to pharmaceutical manufacturing operations. Subpart GGG specifies requirements with regard to information and data used in notifications and compliance reports. Requirements relating to CMS and opacity or visible emissions standards are not applicable.
63.11 - Control Device Requirements for Flares	Applies to pharmaceutical manufacturing operations using flares to comply with standards.
63.12 - State Authority and Delegations	Applies to state authorities regulating air emissions from the pharmaceutical industry.
63.13 - Addresses of State Air Agencies and EPA Regions	Applies; no changes specific to pharmaceutical industry.
63.14 - Incorporation by Reference	Applies; no changes specific to pharmaceutical industry.

Subpart A Provisions	Relevance to GGG
63.15 - Availability of Information and Confidentiality	Applies; no changes specific to pharmaceutical industry.

2.4 Standards

The new emission standards are expressed differently for the various types of sources. In some cases, such as with process vents, one of the standards options is a percentage reduction standard; this allows owners and operators flexibility in achieving the required level of control. In other cases, such as with equipment leaks, it makes more sense to specify work practice standards because it would be difficult, if not impossible, to regularly measure emissions levels from the hundreds of pieces of equipment at a production facility or to require add-on control to reduce the emissions.

The table below provides a summary of the standards in the rule. The pollution prevention option, available for existing sources, is not presented in the table. It is covered in Chapter 10.

TABLE 2-1. STANDARDS FOR NEW AND EXISTING SOURCES

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
Process Vents *	**New**	**Process producing an isolated intermediate**	**$50 ppmv HAP**	• **98% control or** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit or** • **maintain actual emissions less than 900 kg/yr for sum of all vents in a process not controlled to these limits (i.e., 98% or 20 ppmv)** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen (alternative standard)[1]** • **20 ppmv TOC and controlling HCl emissions by at least 95% with a post combustion device scrubber (variation of alternative standard)**

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
	Existing	**Process producing an isolated intermediate**	**$50 ppmv HAP**	• **93% control or** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit or** • **900 kg/yr for the sum of all process vents in a process with a maximum of 1800 kg per year per facility.** • [1] • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen (alternative standard)[1]*** • **20 ppmv TOC and controlling HCl emissions by at least 95% with a post-combustion device scrubber (variation of alternative standard)**
		Large or high emitting vent[1]		• **98% for individual vents[2] (within a process) meeting cutoff based on flow and emissions**

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
Storage Tanks *	**New and existing**	**$ 38 m^3 (10,000 gal) < 75 m^3 (20,000 gal)**	**13.1 kPa (1.9 psia) HAP vapor pressure of liquid stored**	• **90% control, or** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit, or** • **enclosed combustion device w/ minimum res. time of .5 sec at 760EC, or** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit[1*], or** • **use vapor balancing**
		$75 m^3 (20,000 gal)	**$ 13.1 kPa (1.9 psia) HAP vapor pressure of liquid stored**	• **95% control[3], or** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit, or** • **enclosed combustion device w/ minimum res. time of .5 sec at 760EC, or** • **20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit[1*], or** • **use vapor balancing**

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
Wastewater Treatment [5, 6, 7*]	**New and existing**	**>0.25 Mg/yr total HAP load from all POD from PMPU**	**>1,300 ppmw at POD of Table 2 HAP (PSHAP) (annual average concentration)**	• **99% reduction of Table 2 HAP (PSHAP)** • **or to <50 ppmw PSHAP or treat in RCRA unit or** • **95% reduction of total HAP using biotreatment**
			>5,200 ppmw at POD of total HAP load (annual average concentration)	• **99% reduction of Table 2 HAP (PSHAP) or** • **to < 50 ppmw PSHAP and** • **90% reduction of Table 3 HAP (SHAP)** • **or < 520 ppmw SHAP or** • **enhanced biotreatment (for SHAP only and only if PSHAP < 50 ppmw) or** • **95% reduction of total HAP using biotreatment or** • **RCRA unit**
		>1 Mg/yr total HAP load from facility	**>10,000 ppmw at POD of total HAP load (annual average concentration)**	• **99% reduction of Table 2 HAP (PSHAP) or** • **< 50 ppmw PSHAP and** • **90% reduction of Table 3 HAP (SHAP) or** • **< 520 ppmw SHAP or** • **enhanced biotreatment (for SHAP only and only if PSHAP < 50 ppmw) or** • **95% reduction of total HAP using biotreatment or** • **RCRA unit**

Emission Point	New or Existing ?	Applicability		Standard
		Applicability Level	Cutoff	
	New	>1 Mg/yr total HAP load from all POD from PMPU	>110,000 ppmw at POD of Table 3 HAP (SHAP) (annual average concentration)	• 99% reduction of Table 3 HAP (SHAP) or • treat in RCRA unit
Equipment Leaks	New and existing	All components in HAP service where total HAP is $5% by weight	$ 300 hours/yr HAP service	LDAR program

1. Alternative Standard - Outlet limit is 50 ppmv instead of 20 ppmv if noncombustion devices are used.
2. Large Vent - at least 25 tpy uncontrolled HAP emissions from a single process and satisfying flow specifications, note equations in the rule.
3. Refer to discussion of grandfathered vents in section 5.4.1 of this document.
4. For tanks controlled at 90 percent prior to April 2, 1997, no additional control is required.
5. See Chapter 7 on wastewater for more details on vapor suppression and air pollution control device requirements for wastewater and wastewater residuals.
6. Wastewater generated from scrubbers relied upon to control PSHAPs is considered "affected" regardless of concentration.
7. Treatment options are limited if the facility chooses to "designate" wastewater streams (See Chapter 7).

* In addition to the standards listed for process vents, storage tanks, and wastewater treatment, the owner/operator may choose instead to use a flare, compliant boiler, process heater, or RCRA hazardous waste incinerator.

Note: See pages 7-3 and 7-4 for the list of Partially Soluble Hazardous Air Pollutants (PSHAPs) and page 7-4 for the list of Soluble Hazardous Air Pollutants (SHAPs).